



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-638]

Importer of Controlled Substances Application: Novitium Pharma LLC

ACTION: Notice of application.

DATES: Registered bulk manufacturer of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before [INSERT 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. Such persons may also file a written request for a hearing on the application on or before [INSERT 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for a hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on March 2, 2020, Novitium Pharma LLC, 70 Lake Drive, East Windsor, New Jersey 08520, applied to be registered as an importer of the following basic class(es) of controlled substances:

Controlled Substance	Drug Code	Schedule
Lisdexamfetamine	1205	II

The company plans to import the listed controlled substance as a raw material for drug product development and research.

The company may import Active Pharmaceutical Ingredients (API) for research purposes only but not for the manufacturing of Food and Drug Administration-approved products. Approval of permit applications will occur only when the registrant's activity is consistent with what is authorized under **21 U.S.C. 952(a)(2)**.

William T. McDermott,
Assistant Administrator.

[FR Doc. 2020-09705 Filed: 5/6/2020 8:45 am; Publication Date: 5/7/2020]